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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/160,076	09/24/98	SCOTT	D 308072000110

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EXAMINER	
WILSON, M	

ART UNIT	PAPER NUMBER
1633	7

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Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/160,067	Applicant(s) Scott et al.
	Examiner Wilson, Michael C.	Group Art Unit 1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-5, 10-13, 19, and 20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-5, 10-13, 19, and 20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a divisional of application 08/195,874, filed 2-11-94, Patent No. 5,817,308. Claims 6-9, 14-18 and 21-30 have been canceled. Claims 1-5, 10-13 and 19-20 are pending and under consideration in the instant application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 10-13, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zambidis et al. (Feb. 1, 1993, J. Cellular Biochem., Vol. 0, No. 17, Part B, page 251).

Zambidis et al. teach a construct comprising residues 12-26 of the bacteriophage λ cl protein placed at the N-terminus of the IgG1 heavy chain and J588L cells transformed by said construct (see entire abstract). As J588L cells are a myeloma cell line which is a bone marrow tumor cell line, Zambidis et al. clearly anticipates claims 19 and 20. Since expression of the fusion protein occurs in J588L, transcription and translation control regions functional in bone marrow cells are inherently present. Therefore, Zambidis et al. anticipate claims reciting the limitation of control regions as claimed because bone marrow cells are hemopoietic cells. Residues 12-26 of the λ cl protein taught by Zambidis et al. are equivalent to the animo acids 12-26 of the λ CI

repressor protein as claimed. Placing the residues of the λ cl protein at the N-terminus variable region or adjacent to the first framework region of the N-terminus variable region as claimed (claims 3, 10 and 19) is anticipated by Zambidis et al. because the N-terminus of the IgG1 heavy chain is inherently the first framework region of the N-terminus variable region of the chain. Zambidis et al. teach a plasmid vector which is made up of a DNA molecule. As all plasmids are made up of a DNA molecule and are circular, the plasmid of Zambidis et al. has characteristics of the plasmid of claim 13. As there is no disclosure of "characteristics of ATCC No. _____," Zambidis et al. clearly anticipate claim 13. Applicants may overcome this rejection by rewriting claim 13 as "a plasmid of ATCC No...."

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 10-13, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zambidis et al. (Feb. 1, 1993, J. Cellular Biochem., Vol. 0, No. 17, Part B, page 251) in view of Zanetti et al. (Jan. 30, 1992, Nature, Vol. 355, pages 476-477) and Chambers et al. (Feb. 1992, PNAS, USA, Vol. 89, pages 1026-1030).

Zambidis et al. teach a construct comprising residues 12-26 of the bacteriophage λ cl protein placed at the N-terminus of the IgG1 heavy chain and J588L cells transformed by said construct (see entire abstract). As J588L cells are a bone marrow tumor cell line, the bone marrow cells of claim 20 are obvious in view of Zambidis et al. Since expression of the fusion protein occurs in J588L which are hemopoietic cells, transcription and translation control regions functional in hemopoietic cells as written in the claims are obvious in view of the vector of Zambidis et al. Residues 12-26 of the λ cl protein taught by Zambidis et al. are equivalent to the animo acids 12-26 of the λ CI repressor protein as claimed. Placing the residues of the λ cl protein at the N-terminus variable region or adjacent to the first framework region of the N-terminus variable region as claimed (claims 3, 10 and 19) is obvious in view of Zambidis et al. because the N-terminus of the IgG1 heavy chain is the first framework region of the N-terminus variable region of the chain. As there is no disclosure of "characteristics of ATCC No. _____," the plasmid of claim 13 is obvious in view of the plasmid taught by Zambidis et al. Zambidis et al. do not teach using a retroviral vector.

However, at the time of filing, Chambers et al. teach expressing lymphokines in peripheral blood lymphocytes (PBL) which are lymphoid cells using a retroviral construct encoding the b-actin promoter/enhancer (page 1029, column 2, "discussion").

Thus, it would have been obvious to make a construct encoding residues 12-26 of the λ cl protein adjacent to N-terminus of the IgG heavy chain taught by Zambidis et al. using the retroviral construct encoding the b-actin promoter/enhancer taught by Chambers et al. and to

obtain transformed PBLs. Motivation to combine the references is provided by Chambers et al. because the retroviral vector of Chambers et al. is an improved method of transfecting reproducing cells such as lymphoid or hemopoietic cells as claimed which would have been recognized by one of ordinary skill in the art at the time of filing. One of ordinary skill would have recognized the ability to improve transduction in lymphoid cells using the retroviral vector and to express the fusion protein in lymphoid cells to study the immune system which was common at the time of filing. The expression of proteins in T-cells and PBLs as taught by Zanetti and Chambers et al. also indicates the transcriptional and translational control regions function in lymphoid cells as claimed. In addition, control regions that function in T-cells or PBL, such as the b-actin promoter/enhancer found in Chambers et al., were well known in the art at the time of filing to function in lymphoid or hemopoietic cells as claimed. In consideration of the state of the art at the time of filing, one of ordinary skill would have had a reasonable expectation of success in obtaining the vector and cells as claimed.

Thus, Applicants' claimed invention as a whole is clearly *prima facie* obvious in the absence of evidence to the contrary.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 10-13, 19 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 5,817,308, 10-6-98. Although the conflicting claims are not identical, they are not patentably distinct from each other because the composition and methods claim in Patent 5,817,308 require a vector comprising a DNA sequence encoding a fusion immunoglobulin heavy chain, light chain, or both heavy and light chains, operably linked to transcriptional and translational control regions functional in said cells, and which fusion immunoglobulin comprises one or more heterologous tolerogenic epitopes, to which said animal is being tolerized, fused to the variable region of said immunoglobulin heavy or light chain and cells stably transformed with said vector. Thus, given the composition and method claims of Patent 5,817,308, the expression vector and cells claimed in the instant invention would be obvious, as the only use defined for the vector in the specification is for inducing and maintaining tolerance (page 2, line 20).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 is indefinite because the ATCC Number of the plasmid has not been filled in and because the term "characteristics" is not defined in the specification and may have various meanings in the art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian R. Stanton, can be reached on (703) 308-2801. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

Michael C. Wilson
May 7, 1999

BRIAN R. STANTON, PH.D
PRIMARY EXAMINER